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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/533,790	05/04/2005	Ingemar Berndtsson	0091-0245PUS1	4572

2292 7590 12/04/2008
BIRCH STEWART KOLASCH & BIRCH
PO BOX 747
FALLS CHURCH, VA 22040-0747

EXAMINER

RAMDHANIE, BOBBY

ART UNIT	PAPER NUMBER
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1797

NOTIFICATION DATE	DELIVERY MODE
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12/04/2008

ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

mailroom@bskb.com

Office Action Summary	Application No. 10/533,790	Applicant(s) BERNDTSSON ET AL.	
	Examiner BOBBY RAMDHANIE	Art Unit 1797	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 02 September 2008.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 10-27 is/are pending in the application.
- 4a) Of the above claim(s) 18-27 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 10-13, 16 and 17 is/are rejected.
- 7) ☒ Claim(s) 14 and 15 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 05/04/2005 & 05/09/2008 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|----------------------------------------------------------------------------------------|-------------------------------------------------------------------|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>05/04/2005 & 05/09/2008</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Election/Restrictions

1. Applicant's election with traverse of Group I Claims 10-17 in the reply filed on 09/04/2008 is acknowledged. The traversal is on the ground(s) that the International Search Report factually stated that the instrument and method claims in the single application were so linked to form a single general inventive concept and that MPEP Section 803 states the proper requirements for making a restriction in an application.

This is not found persuasive because of the following:

2. A). The international search report is an opinion of the international searching authority and is not exhaustive complete search. MPEP 1800, Article 35 specifically states that the report is an "opinion." The ISR report only lists the limited areas of search - which explicitly shows that not all databases are searched and to what extent they may have been searched.

3. B). Applicants have filed the instant application under 35 U.S.C. 371. Restriction practice under the filings of these applications is governed by MPEP 1800.

The requirement is still deemed proper and is therefore made FINAL.

Allowable Subject Matter

4. Claims 14 & 15 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

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5. The following is a statement of reasons for the indication of allowable subject matter: Claims 14 & 15, recite the limitation of a slide valve that interconnects selected channels between selected receptacles. The prior art of record does not disclose nor suggest this limitation in a blood testing apparatus.

Claim Rejections - 35 USC § 102

6. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

7. Claims 10 & 16 are rejected under 35 U.S.C. 102(b) as being anticipated by MILEAF ET AL (US5652149).

8. Applicants' claims are toward a device.

9. Regarding Claims 10 & 16, MILEAF ET AL discloses the disposable cartridge for use in blood testing comprising: A). A housing including a generally flat top side and multiple depressions formed on said top side, each of said depressions defining a main portion of a receptacle and connecting to at least one of channels disposed within said housing (See Figure 1 housing – Items 12 & 30, depressions on top side - Item 16); B). A diaphragm sealingly attached to said top side of said housing, covering said multiple depressions and forming multiple said receptacle; portions of said diaphragm over said depressions being flexible (See Figure 1 Item 36); and C). A valve disposed within said housing among said channels adapted to interconnect selected channels for directing

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flow between selected receptacles (See Figure 2 Item 52 or Figures 3 & 4 the combination of Items 56,58,& 54 which reads on the valve in the instant claim).

10. Additional Disclosures Included: Claim 16: Said housing has integrated therein a light path for performing photometric measurement on material contained in at least one of said receptacles (See Figure 1 Item 38 or Figures 13A-D Item 38, the optical window or Light path is capable of performing measurements on material contained in at least one of said receptacles).

11. Claims 10-13 & 16 are rejected under 35 U.S.C. 102(b) as being anticipated by SOUTHGATE ET AL (US5863502).

12. Applicants' claims are toward a device.

13. Regarding Claims 10-13, 16, SOUTHGATE ET AL discloses the disposable cartridge for use in blood testing comprising: A). A housing including a generally flat top side and multiple depressions formed on said top side, each of said depressions defining a main portion of a receptacle and connecting to at least one of channels disposed within said housing (See Figure 1 housing – Item 100, depressions on top side – Figure 1 see chambers); B). A diaphragm sealingly attached to said top side of said housing, covering said multiple depressions and forming multiple said receptacle; portions of said diaphragm over said depressions being flexible (See Figure 2C, multiple depressions with a Bursapak film on top); and C). A valve disposed within said housing among said channels adapted to interconnect selected channels for directing flow between selected receptacles (See Figure 1A Item 180).

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Additional Disclosures Included: Claim 11: One or more of said depressions includes a sealed opening adapted to interface with a needle of a cell counting device (See Figure 1B Item 150 (depression) and Item 151 (inlet) which is sealed by the film (See Column 11 lines 17-20); Claim 12: At least one of said receptacles contains a liquid diluting agent (See Figure 1 Item 150 a fluid may define a diluting agent & See Column 12 lines 59-61 lysing reagents and washing buffers may define diluting agents); and Claim 13: One of said receptacles contains a haemolysis agent (See Column 28 lines 16-46 in particular Tris:HCl); Claim 16: Said housing has integrated therein a light path for performing photometric measurement on material contained in at least one of said receptacles (See Column 23; Detection Devices).

Claim Rejections - 35 USC § 103

14. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

15. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

16. Claims 11-13 is rejected under 35 U.S.C. 103(a) as being unpatentable over MILEAF ET AL.

17. Applicants' claims are toward a device.

18. Regarding Claims 11-13, MILEAF ET AL discloses the disposable cartridge of Claim 10, except wherein one or more of said depressions includes a sealed opening adapted to interface with a needle of a cell counting device. MILEAF ET AL does however disclose filling the reagent reservoir through fill holes in Figure 1 Item 40. It would have been obvious to one of ordinary skill in the art at the time the invention was made to seal these holes (which is capable of being interfaced with a needle for any type of device) because if it was not sealed, the reagents would drip out.

19. Additional Disclosures Included: Claim 12: At least one of said receptacles contains a liquid diluting agent (See Column 5 lines 11-15, reagent storage reservoirs which store the buffered liquid reagents inherently dilute samples they act upon); and Claim 13: One of said receptacles contains a haemolysis agent (See Column 6 lines 60-66, sucrose is a haemolysis agent. Examiner reads haemolysis as hemolysis).

20. Claim 17 is rejected under 35 U.S.C. 103(a) as being unpatentable over STONEGATE ET AL.

21. Applicants' claim is toward a device.

22. For Claim 17, STONEGATE ET AL discloses the disposable cartridge of claim 10 further comprising an additional depression sealed by said diaphragm forming an additional receptacle; said additional depression having a sealed opening adapted to

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interface with a needle of a cell counting device (See Figure 4B Items 251A, 251B, 252A (chambers) & Items 231 and 232 (inlets)). STONEGATE ET AL does not disclose said additional receptacle containing a washing liquid for cleaning said cell counting device. It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the cartridge of STONEGATE ET AL with a washing liquid for cleaning said cell counting device as a design choice since STONEGATE ET AL discloses that the cassettes may be used for ELISA assays which tests blood for the presence of antibodies to the AIDS virus (See Column 31 lines 15-17).

Telephonic Inquiries

Any inquiry concerning this communication or earlier communications from the examiner should be directed to BOBBY RAMDHANIE whose telephone number is (571)270-3240. The examiner can normally be reached on Mon-Fri 8-5 (Alt Fri off).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Walter Griffin can be reached on 571-272-1447. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/B. R./

/Walter D. Griffin/
Supervisory Patent Examiner, Art Unit 1797